

MARKED-UP COPY OF AMENDED CLAIMS:

1. (Amended) A method of administration of an active ingredient to a mammal through a transmucosal route, said method comprising:

a. delivering said active ingredient to a desired site in a body of said mammal; and, sequentially, at said desired site,

i. adjusting a localized environment of said active ingredient to promote dissolution of said active ingredient,

ii. adjusting said localized environment to promote absorption of said active ingredient.

~~b. promoting dissolution of said active ingredient,~~

~~c. promoting absorption of said active ingredient.~~

2. (Amended) The method of claim 1, wherein said active ingredient is delivered in a dosage form having a first portion and a second portion;

said step of adjusting said localized environment to promote ~~promoting~~ said dissolution comprising releasing said first portion of said dosage form;

said step of adjusting said localized environment to promote ~~promoting~~ said absorption comprising releasing said second portion of said dosage form.

12. (Amended) The method of claim 5, wherein said dosage form includes means for said sequential release of said first portion and said second portion, said means for sequential release selected from the group consisting of coatings, membranes, matrix materials, pre-cursors of active ingredients and pre-cursors of pH-adjusting substances.

20. (Amended) A method for administering an active ingredient via a transmucosal route in a mammal, comprising administering said active ingredient in a dosage form with a first pH-adjusting substance and a second pH-adjusting substance thereby ~~so that~~

~~said first pH-adjusting substance attains peak activity in the localized environment of the active ingredient before said second pH-adjusting substance attains peak activity in the localized environment of the active ingredient, whereby~~ the localized environment of the active ingredient attains a first pH and then a second pH, said first pH promoting dissolution of said active ingredient and said second pH promoting absorption of said active ingredient.

20. (Amended) The method of claim ~~47-49~~, wherein said first and said second pH-adjusting substances are respectively an acid and a base.

21. (Amended) The method of claim ~~47-49~~, wherein said first and said second pH-adjusting substances are respectively a base and an acid.

22. (Amended) The method of claim ~~47-49~~, wherein said first and said second pH-adjusting substance are respectively a base and a base.

23. (Amended) The method of claim ~~47-49~~, wherein said first and said second pH-adjusting substances are respectively an acid and an acid.

25. (Amended) The method of claim ~~47-49~~, wherein said transmucosal route is selected from the group consisting of buccal, sublingual, gingival, gastrointestinal, rectal, vaginal, and nasal.

25. (Amended) The method of claim ~~47-49~~, wherein said active ingredient is selected from the group consisting of analgesics, anti-inflammatories, antipyretics, antibiotics, antimicrobials, laxatives, anorexics, antihistamines, antiasthmatics, antidiuretics, antifatulents, antimigraine agents, antispasmodics, sedatives, antihyperactives, antihypertensives, tranquilizers, decongestants, beta blockers, peptides, proteins, and oligonucleotides.

26. (Amended) The method of claim ~~47-49~~, wherein said administering step includes providing said second pH-adjusting substance dispersed in a controlled release matrix material in said dosage form.

27. (Amended) The method of claim 2625, wherein said active ingredient is peripheral to said controlled release matrix material in said dosage form.

28. (Amended) The method of claim 4719, wherein said administering step includes providing said second pH-adjusting substance surrounded by a coating, wherein said first pH-adjusting substance is peripheral to said coating in said dosage form.

30. (Amended) The method of claim 4719, wherein said administering step includes providing said second pH-adjusting substance surrounded by a membrane, wherein said first pH-adjusting substance is peripheral to said membrane in said dosage form.

32. (Amended) A pharmaceutical composition comprising an active ingredient in a dosage form comprising a first portion, a second portion and means for sequential release of said first portion and said second portion at a desired site; said first portion including one or more first substances that adjust a localized environment of said active ingredient at said desired site to promote dissolution of said active ingredient; said second portion including one or more second substances that adjust said localized environment of said active ingredient at said desired site to promote absorption of said active ingredient.

REMARKS


Claims 1-46 are pending in the above-identified patent application. By this Preliminary Amendment, Applicants have amended claims 1-2, 12, 19-28, 30, and 32, and added new claim 47.

The above-noted amendments to the claims are respectfully submitted in order to more clearly and appropriately claim the subject matter that Applicants consider to constitute their inventive contribution. No new matter is included. The claims are supported in the application as filed. In view of the above, it is respectfully requested that these amendments now be entered.

If for any reason the Examiner does not believe such action can be taken, it is respectfully requested that the Examiner contacts the undersigned counsel at (908) 654-5000 in order to overcome any objections. If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge applicant's Deposit Account No. 12-1095 therefor.

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Respectfully submitted,

By 
Edward D. Pergament
Registration No.: 43,346
LERNER, DAVID, LITTENBERG,
KRUMHOLZ & MENTLIK, LLP
600 South Avenue West
Westfield, New Jersey 07090
(908) 654-5000
Attorneys for Applicant

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